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Registration Decision RD2013-21

Ammonia (Present as Ammonium Sulfate)

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Registration Decision for Ammonia present as Ammonia Sulfate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of the technical product Fennosurf 583-T and the end-use product Fennosurf 583-C, containing the technical grade active ingredient ammonia (present as ammonium sulfate), to control bacteria and fungi in pulp and paper mills.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-02, *Ammonia (Present as Ammonium Sulfate)*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for ammonia (present as ammonium sulfate) and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2013-02.

For more details on the information presented in this Registration Decision, please refer to PRD2013-02, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Ammonia (present as Ammonium Sulfate)?

Ammonia (present as ammonium sulfate) is the active ingredient in the end-use product Fennosurf 583-C which is proposed to control bacteria and fungi in pulp and paper mills.

Ammonium sulfate provides a source of ammonia (NH_3). The active ingredient of the Fennosurf 583-C treatment is monochloramine (NH_2Cl), which is being generated *in situ* when the ammonia from the ammonium sulfate reacts with the sodium hypochlorite. This reaction occurs through a dispensing device mixing sodium hypochlorite and Fennosurf 583-C. Monochloramine is known to kill cells by destroying and/or impairing cell walls as well as inhibiting proteins.

Health Considerations

Can Approved Uses of Ammonia (present as Ammonium Sulfate) Affect Human Health?

Ammonia (present as Ammonium Sulfate) is unlikely to affect human health when it is used according to label directions.

Exposure to ammonia (present as ammonium sulfate) may occur when handling the end-use product, Fennosurf 583-C (7.73 % ammonia present as ammonium sulfate), which has a proposed commercial use as an antimicrobial product intended for pulp and paper mills. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, Fennosurf 583-T (25.5 % ammonia present as ammonium sulfate), is considered to be of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is slightly irritating to eyes and skin, and is not expected to be a dermal sensitizer. Precautionary statements alerting users to the potential for eye and skin irritation are required on both the technical grade active ingredient and end-use product labels.

Dermal or inhalation exposure is possible for workers performing loading, clean-up and repair activities involving the end-use product, Fennosurf 583-C, and for workers engaged in post-application activities such as coupling or uncoupling transfer lines. Accidental exposure to the eyes may occur if the product is splashed during handling. Therefore, precautionary measures including personal protective equipment are required on the end-use product label to mitigate such exposure concerns. The potential for bystander exposure is expected to be minimal as non-workers are not expected to be present in the wastewater treatment plant, and the end-use product is to be used in a closed system.

Residues in Water and Food

The proposed use of Fennosurf 593-C is for treatment of process waters in the production of non-food contact paper. Dietary intake is not anticipated.

No risk due to exposure from drinking water is anticipated.

Occupational Risks From Handling Fennosurf 583-C

Occupational risks are not of concern when Fennosurf 583-C is used according to label directions, which include protective measures.

Occupational exposure to individuals handling Fennosurf 583-C is not expected to result in unacceptable risk when the product is used according to label directions.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the label aimed at mitigating exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Ammonia (present as Ammonium Sulfate) Is Introduced Into the Environment?

Ammonia (present as ammonium sulfate) is to be used in pulp and paper mills process water systems for the control of bacteria and fungi. The product is applied in conjunction with sodium hypochlorite to form monochloramine, a slow-acting oxidizing microbicide. Monochloramine, which is the primary chemical of environmental concern with the use of Fennosurf 583-C, could potentially enter the environment through industrial effluent discharge. Discharges can be to both freshwater and marine water bodies, as industrial facilities where this product is to be used can be located near both types of aquatic environments. Due to biological degradation during effluent treatment processes, and through chemical activity within the treatment system, levels of monchloramine discharged to the environment through effluent are expected to be very low. However, the chemical is toxic to aquatic organisms, and label statements requiring dechlorination of effluent to undetectable concentrations will be required prior to discharge, where applicable.

Value Considerations

What Is the Value of Fennosurf 583-C?

Fennosurf 583-C is used for the control of bacteria and fungi growth in pulp and paper mills.

In pulp and paper mills, the microorganisms such as bacteria and fungi must be controlled. These organisms can produce biofilms (slimes) on process equipment. Biofilms can also produce hydrogen sulfide, which is corrosive to machinery. Sloughing off of the biofilms leads to defects in the final paper sheet and disruptions of the paper making process. This results in a lower efficiency in the paper making process. In addition, bacteria and fungi growth can lead to spoilage of pulp resulting in significant waste and economical losses. Fennosurf 583-C will provide a source of ammonia to be mixed with sodium hypochlorite to generate monochloramine. This new active ingredient provides an alternative for the treatment of free floating bacteria and fungi in fouled paper systems.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Fennosurf 583-C to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The statements 'May irritate eyes and skin', 'Avoid contact with skin, eyes and clothing', 'Avoid breathing vapour or spray mist' are required on the secondary display panel of the technical grade active ingredient end-use product labels.

The personal protective equipment for all loading, cleanup and repair activities required on the end-use product label includes protective eyewear, coveralls or long pants and long sleeved shirt, chemical resistant gloves, socks and chemical resistant footwear.

Environment

Label statements necessitating dechlorination of effluent to non-detectable concentrations when monochloramine residuals (measured as total chlorine, Cl_2) are detected prior to discharge are required.

A label statement indicating toxicity to aquatic organisms is required.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-02, *Ammonia (Present as Ammonium Sulfate)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

A comment was received on the formation of undesirable products other than monochloramine

With regard to the product Fennosurf 583-C, a concern was raised regarding the production of by-products other than monochloramine through the reaction of sodium hypochlorite and ammonia if the reaction process was not controlled adequately. The concern is that these products, should they occur, could be potentially harmful to the environment and should be discussed further in PMRA documentation.

Response

The reaction between sodium hypochlorite and ammonia is managed through the control of pH, and also by restricting the proportion of each substance to be used in the feed system. Monochloramine will be the dominant species formed when sodium hypochlorite and ammonia are mixed in a ratio of 5:1 or less. The mixing volumes specified on the Fennosurf 583-C product label equate to a 2:1 ratio, and these are required to be used at all times throughout the process. This ratio is lower than 5:1. These label instructions were reviewed by the PMRA and determined to be adequate and effective for controlling the levels of monochloramine that may be produced. By-products other than monochloramine created through this reaction are expected to be limited. However, any chemical by-products remaining in the effluent at the point of discharge, as well as the effluent itself, would be subject to environmental requirements set out by other municipal, provincial and federal permits and regulations (such as the Environmental Effects Monitoring program, which falls under the jurisdiction of the *Fisheries Act*), as well as any relevant risk management strategies addressing substances identified as toxic under *Canadian Environmental Protection Act*. Furthermore, concentrations of these chemical by-products are expected to be much lower than those produced from pulp bleaching.

A comment was received regarding hydrogen sulphide

A concern was raised regarding the production of hydrogen sulphide through bacterial conversion of sulphur, which is added to the process water from the use of Fennosurf 583-C. The respondent indicated that the potential impact on the environment of this added amount of hydrogen sulphide being discharged should have been taken into consideration.

Response

Sulphur is present in the raw materials used in pulp and paper mills, and the amount being added as ammonium sulfate through the use of Fennosurf 583-C is not expected to be of environmental significance. For any sulphur present as a result of the use of Fennosurf, transformation to hydrogen sulphide is expected to be limited as such compounds would be produced primarily under acidic anaerobic conditions only. Such conditions do not normally occur in effluent or in most receiving environments where pulp mill effluent is discharged. However, where this could be produced, total reduced sulphur is subject to reporting by the industry to the National Pollutant Release Inventory.